

Food and Drug Administration College Park, MD 20740

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AUG 3 1 2004

Aileen S. Trant, Ph.D.
Director Research & Development
Daily Wellness Company
275 Santa Ana Court
Sunnyvale, California 94085

Dear Dr. Trant:

This is in response to your letter of July 16 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Daily Wellness Company is making the following claim, among others, for the product TEAZ Relief:

"[S]oothe Cold and Flu Symptoms."

"Echinacea...used to treat infections and respiratory problems, is combined with Zinc and Vitamin C to clinically reduce severity and duration of cold and flu symptoms."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate disease, namely influenza and the common cold. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

## Page 2 - Dr. Aileen S. Trant

Please contact us if we may be of further assistance.

Sincerely yours,

Susan J. Walker, M.D.

Director

Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety

Center for Food Safety and Applied Nutrition

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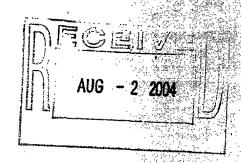
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310 FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Los Angeles District Office, Office of Compliance, HFR-PA-240



July 16, 2004

Vincent Keyes Food and Drug Administration HFS-810 Room 1838 200 C Street SW Washington, DC 20204



As per section 6 of the Dietary Supplement Health and Education Act of 1994, I respectfully submit the following information for:

The Daily Wellness Company 275 Santa Ana Court Sunnyvale, CA 94085

Product and claims to be filed:

TEAZ Relief™

Healing Lemon Flavor

A Powerful Blend of Echinacea, Zinc and Vitamin C to Soothe Cold and Flu Symptoms.

Echinacea, a native American herb used to treat infections and respiratory problems, is combined with Zinc and Vitamin C to clinically reduce severity and duration of cold and flu symptoms.\* The healing flavors of tea and lemon provide soothing relief either hot or cold.

I hereby certify that the information contained in the above notice is complete and accurate, and that The Daily Wellness Company has substantiation that the statements are truthful and not misleading.

Sincerely,

Aileen S. Trant, Ph.D.

Director, Research & Development

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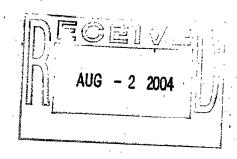
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Sincerely,

Aileen S. Trant, Ph.D.

Director, Research & Development

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Execution Committee Commit Cold and if Symptoms. CA CASH REFUND MI 104 DEPOSIT VT ME NY OR MA IA CT 54

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